

## **Vision for Regulation of Veterinary Medicines across the World**

**Vision for 2025:** Efficient regulatory systems that result in harmonized, science-based decisions in predictable timeframes, resulting in the wide availability of safe and effective veterinary medicines.

### **Background – Current Situation**

The [2015 Global Benchmarking Report](#) provides a good basis for considering the future needs for the regulatory system for veterinary medicines; this includes, but is not limited to the countries and regions covered by the benchmarking report.

The report reveals significant differences between countries or regions, for example in terms of maturity of the regulatory framework, the different types of application procedures available, the different ways in which changes to products are managed, the approach to monitoring safety and efficacy of products after registration, the transparency of the Authorities and resources available to the Authorities.

Many of the differences are fundamental and are based on different philosophies and level of trust placed in the veterinary pharmaceutical industry. It is not simply that some Authorities have light weight versions of the framework used in other regions, the frameworks themselves differ.

### **Why Regulatory Harmonisation is Essential**

The veterinary pharmaceutical industry continues to consolidate through mergers and acquisitions. Funding for research and development (R&D) in particular to support old veterinary medicines or veterinary medicines serving small markets, whether in countries, for particular species or for particular diseases, is under intense pressure.

It is important to take into account that the cost of development of a new veterinary medicine for use in food animals is extremely high. For example, in the USA for a new livestock pharmaceutical product the average develop cost is US\$ 32 million, and a proportion of the available R&D budget in companies (15-31% depending on the region) has to be used to defend existing products. It is necessary to maximise the outputs of new products from the available R&D budgets, so that as well as ensuring efficient use of the money to support new products, less of the money should be side-tracked to keep existing products on the market.

To maximise innovation and the available medicines to animals and customers, it is important to remove unnecessary administrative burdens and to achieve regulatory convergence between countries/regions.

The danger is that if insufficient worldwide progress is made in these areas, there will be an even narrower range of veterinary products registered /distributed. It is already the case that veterinarians in some countries do not have access to fundamental veterinary medicines such as effective anthelmintic, antibiotics, vaccines, anaesthetics, etc. For example, even in Europe, fairly affluent countries such as Finland have very few authorised veterinary medicines.

If the right steps are not taken the number of countries with fewer and fewer products available could increase further, not only damaging animal health and welfare, but also with negative implications for public health in the case of zoonotic diseases. Furthermore, there are implications for the economy in the country if farmers cannot access appropriate veterinary medicines, as their efficiency in meat/milk/egg etc. production is reduced if their animals are not kept healthy. Whilst a small number of new innovative veterinary medicines will always be registered it is likely these numbers will reduce over

time and will be limited to a small and elite group of countries, the cost of the medicine is likely to be high and so potential benefits will be limited.

It is therefore essential that any new country/Authority initiatives do not actually lead to further divergence and that instead progress is made in achieving regulatory convergence and reducing administrative burdens, as set out in the 2025 vision.

### **What are the key components of the Vision for Regulation across the World in 2025?**

The **ten point plan** supporting the Vision is:

1. Authorisation decisions are science-based solely on evaluation of benefit and risks, with no differentiation in requirements approach between local and other manufacturers, and reached by individuals with no conflicts of interest.
2. Predictable regulatory timeframes for consideration of applications, with no assessment taking longer than 24 months for a new product, and no longer than 12 months for significant changes to existing products, with all simple changes with no impact on safety and efficacy not requiring applications. Accelerated assessment pathways (less than 6 months) in place for vaccines and pharmaceuticals which are required to help tackle new emerging serious diseases.
3. Regulation which is efficient for industry and regulators, which enables industry to focus efforts in areas which genuinely support/maintain the quality, safety and efficacy of veterinary medicines whilst reassuring users/consumers i.e. removal of unnecessary administrative burden imposed by individual Regulatory Authority requirements and/or created by different or even contradictory Regulatory Authority requirements.
4. More countries/regions co-operating on the core assessment of the same product, or mutually recognising assessments from other countries/regions. Specifically implementing already existing schemes (in Africa – Southern African Development Community) and introducing new schemes.
5. A fair return on investment for innovation. All products having to demonstrate quality, safety and efficacy. Generic products having to demonstrate appropriate quality and bioequivalence in order to confirm safety and efficacy. Maintaining confidentiality of data as well as awarding appropriate protection of data (at least 10 years for new products) and hence fair returns on investment in the case of new veterinary medicines and for already registered products (5 years) where significant new data are generated.
6. Regulatory frameworks and regulatory staff which can manage highly innovative products/new technologies. Regulatory frameworks need to be written so that they do not hinder future innovation and so that regulators can interpret them in a flexible way. Regulatory staff needs suitable training on new technologies, or access to impartial expertise for example from academia.
7. Ability for companies to undertake global developments, with a core set of data and studies meeting the needs of all countries/regions. VICH conducted studies being accepted by all countries, with additional local clinical and/or safety studies only being required where there are differences in relevant factors such as breeds, husbandry, etc.

8. Ability to locate manufacturing anywhere in the world, operating to a single set of standards. More mutual recognition agreements on inspections are necessary to avoid manufacturing sites being inspected by multiple Agencies with different degrees of expertise. Quality standards applied to products intended for a specific country/region are appropriate and at the same level irrespective of the location of the manufacturing site.
9. Ability for companies to operate a single system of pharmacovigilance for the same product. With requirements and approach aligned with the HealthforAnimals description of a basic pharmacovigilance system and relevant VICH guidelines. Countries being responsible for evaluation and monitoring of events which occur in their country and not elsewhere.
10. Countries to have legal frameworks which include a cascade of what medicines may be used in animals, registered veterinary medicines being at the top of hierarchy. Appropriate Authority enforcement to deal with illegal (or illegally supplied) veterinary medicines.

In addition, **for vaccines** there are some additional elements:

- a) For individual batches already performed, safety tests at the manufacturing site are not required to be repeated.
- b) For inactivated vaccines with a proven record of manufacture, safety tests in the target species are not required for the purpose of batch release.
- c) For vaccines produced using biotechnology, the regulatory framework applied is characterised by the fact that the product is a vaccine, and not specifically by the technology used in manufacture, with an appropriate balance in the assessment between benefits and risks.
- d) Terminology used for example in labels, leaflets, public assessment reports is appropriate, being accurate whilst avoiding negative connotations.